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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,729	10/10/2000	John D. Nguyen	3311.020US0	7128

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EXAMINER

HOEY, ALISSA L

ART UNIT

PAPER NUMBER

3765

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/686,729

Applicant(s)

NGUYEN ET AL.

Examiner

Alissa L. Hoey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Adams (US 6,346,112).

Adams provides a method of providing clips each having two end points which are separated from each other when the clip is in an open configuration and returns to a closed configuration by reducing the distance between the end points. The clips are placed around an annulus by causing both of the two end points of each of the clips in the open configuration to penetrate tissue of the annulus at two circumferentially separated positions whereby the clips reduce the diameter of the annulus (figure 1A, 1B). The two end points of the clips are connected through a flexible member to a tissue-piercing needle and the clips are placed around the annulus each by causing the associated one of needles connected thereto to penetrate the tissue at one position and to come out at another position which is circumferentially separated from the one position (column 11A, 11B). The clips are loaded in a clip delivery device and a specified number of the clips are pushed out of the delivery device penetrating tissue simultaneously (figure 6). The clips are generally U-shaped when in the open configuration comprising a wire of a shape memory material (column 2, lines 50-61). An

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outer tube extending in a longitudinal direction and having an elongated slit at one end. The pusher (93) being elongated and adapted to slide in the longitudinal direction inside the outer tube and to push the specified number of clips through the slit. A pair of cylindrical cartridges coaxially disposed with a gap there between and adjacent the slit. The clips being mounted in the open configuration to the cartridges. The gap being wide enough to allow only the specified number of clips to pass therethrough at a time and a pair of springs for pushing the clips over and along the cartridges toward the gap (column 4, lines 19-67).

3. Claims 9-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Kuehn et al. (US 6,165,183).

Kuehn provides a mitral valve repair method of providing clips each having two end points that are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between the end points when in the open configuration. Placing an annuloplasty ring about the annulus and attaching the ring around the annulus by causing the clips to pass through the ring (figures 1-44). The clips are attached to the ring in circumferential directions along the ring (figure 25A-31). The clips have a tissue penetrating needle releasably attached through a flexible member to one of the two end points thereof. Attaching the ring by causing the needle associated with the clips to penetrate and pass through the ring and tissue of the annulus by Pulling the flexible member to position each clips so as to hold the ring to the tissue. The needle is caused to pass through the tissue at two positions separated by a shorter distance to penetrate the tissue at one position and to

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come out at another position (figures 25-32). The clips are generally U-shaped when in the open configuration comprising a wire of a shape memory material (column 12, lines 14-26). The clips have a tissue-penetrating needle that is releasable attached through a flexible member to each of the two end points thereof. The step of attaching the ring causing each of the needles of the clips to penetrate and come out of the annulus and to pass through the ring. The flexible members are pulled to position and the clips hold the ring to the tissue (column 11, lines 20-35). Placing a prosthesis sewing cuff therefore where the valve portions have been removed and attaching the prosthesis sewing cuff to the tissue around the removed valve by causing the clips to penetrate both the prosthesis sewing cuff and the tissue (column 12, lines 27-67). The prosthesis sewing cuff is attached by causing the needle associated with each clip to penetrate and pass through the prosthesis sewing cuff and tissue of the annulus. Pulling the flexible member to position the clip so as to hold the prosthesis sewing cuff to the tissue (column 13, lines 1-65).

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gabbay et al., Gardiner et al., Adams, Gilbertson et al., Taheri, Grunwald, Mers Kelly et al., Bolduc et al. and Gardiner et al. are all cited to show closely related medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alissa L. Hoey whose telephone number is (703) 308-6094. The examiner can normally be reached on M-F (8:00-5:30)Second Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

alh  
July 9, 2002

  
GLORIA M. HALE  
PRIMARY EXAMINER